

Food and Drug Administration, HHS

§ 812.1

been granted or denied. FDA will respond to a written request for termination of a cease distribution and notification or recall order within 30 working days of its receipt.

§ 810.18 Public notice.

The agency will make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new mandatory recall issued under § 810.13. The agency will delay public notification of orders when the agency determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

Subpart A—General Provisions

- Sec.
- 812.1 Scope.
- 812.2 Applicability.
- 812.3 Definitions.
- 812.5 Labeling of investigational devices.
- 812.7 Prohibition of promotion and other practices.
- 812.10 Waivers.
- 812.18 Import and export requirements.
- 812.19 Address for IDE correspondence.

Subpart B—Application and Administrative Action

- 812.20 Application.
- 812.25 Investigational plan.
- 812.27 Report of prior investigations.
- 812.30 FDA action on applications.
- 812.35 Supplemental applications.
- 812.36 Treatment use of an investigational device.
- 812.38 Confidentiality of data and information.

Subpart C—Responsibilities of Sponsors

- 812.40 General responsibilities of sponsors.
- 812.42 FDA and IRB approval.
- 812.43 Selecting investigators and monitors.
- 812.45 Informing investigators.
- 812.46 Monitoring investigations.
- 812.47 Emergency research under § 50.24 of this chapter.

Subpart D—IRB Review and Approval

- 812.60 IRB composition, duties, and functions.
- 812.62 IRB approval.

- 812.64 IRB's continuing review.
- 812.65 [Reserved]
- 812.66 Significant risk device determinations.

Subpart E—Responsibilities of Investigators

- 812.100 General responsibilities of investigators.
- 812.110 Specific responsibilities of investigators.
- 812.119 Disqualification of a clinical investigator.

Subpart F [Reserved]

Subpart G—Records and Reports

- 812.140 Records.
- 812.145 Inspections.
- 812.150 Reports.

AUTHORITY: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

SOURCE: 45 FR 3751, Jan. 18, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 812.1 Scope.

(a) The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose. This part provides procedures for the conduct of clinical investigations of devices. An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued thereunder: Misbranding under section 502 of the act, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section 516, records and reports